

DOC 930012
FINAL

DATA EVALUATION REPORT

TREO TM SPF 15, 3-Way Protecting Lotion

Study Type: Primary Ocular Irritation in Rabbits

Prepared for:

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Environmental Protection Agency
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DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-4 and 152-13: Primary ocular irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901

MRID Number: 421513-07

TEST MATERIAL: TREO TM SPF 15, 3-way protecting lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Laboratories, Inc., 950 Third Avenue, New York, NY

STUDY NUMBER: 90033-2

TESTING FACILITY: Consumer Product Testing Company, Inc., 12 Spielman Road, Fairfield, NJ

TITLE OF REPORT: Primary Ocular Irritation in Rabbits

AUTHOR: Steven Nitka

STUDY COMPLETED: February 23, 1990

CONCLUSIONS: TREO TM SPF 15, 3-way protecting lotion is a minimal ocular irritant over 72 hours to rabbits.

CORE CLASSIFICATION: Core Supplementary. This study was classified as Core Supplementary according to Guideline series 81-4 and 152-13 because the eyes were not examined for ocular effects at 1 hour, and purity and stability of the test substance were not reported. The average Draize scores at 24, 48, and 72 hours were 2.0, 0.3, and 0.0, respectively.

TOXICITY CATEGORY: IV--Caution

A. MATERIALS

1. Test Material

Test material: TREO TM SPF 15, 3-way protecting lotion
Purity: Not reported
Physical description: Off-white lotion (as reported in an acute dermal study (MRID# 421513-05)).
Lot number: Not reported
Storage conditions: Not reported
Stability: Not reported

2. Controls

Animals: None needed
Test substance: None needed

3. Test Animals

Species: Rabbit
Strain: New Zealand white
Source: Not reported-- study report indicated animals were obtained from a suitably licensed dealer.
Sex: Unspecified
Numbers: Six
Housing: Individual
Acclimation: At least 3 days
Age: Three months
Weight: ~2 kg
Feeding: Feed (Agway Pro-Pet Big Red Rabbit Feed) and water provided ad libitum.
Selection: Animals in good condition and with no visible ocular defects or irritation were chosen.

4. Exposure

Route of administration: Ocular
Dose level: 0.1 mL

B. TEST PERFORMANCE

A single dose of 0.1 mL of the test article was placed in the conjunctival sac of one eye of each animal. The test article was used as received. The eyelids were held together for 1 second to prevent loss of the material. The other eye remained untreated and served as the control. The eyes of all animals remained unwashed for 24 hours. Using the Draize scoring system, the eyes were examined for corneal opacity, iritis, and conjunctivitis at 24, 48, and 72 hours after treatment, and at 4 and 7 days if irritation persisted (see Appendix, CBI Tables 1 and 2).

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

Neither corneal opacity nor iritis was seen in any of the rabbits during the study. At 24 hours, conjunctival redness (grade 1) was seen in 4 of 6 rabbits, and conjunctival chemosis and discharge was seen in one rabbit. At 48 hours, conjunctival redness (grade 1) was seen in only 1 rabbit. By 72 hours, all irritation was resolved. The average Draize scores at 24, 48, and 72 hours were 2.0, 0.3, and 0.0, respectively. Based on these

scores, the study author concluded that TREO TM SPF 15, 3-Way protecting lotion was a minimal ocular irritant to rabbits.

D. QUALITY ASSURANCE MEASURE

A signed Quality Assurance Statement was presented, but not dated. A Good Laboratory Practice compliance statement was included.

E. REVIEWERS' COMMENTS

The reviewers agree with the study author's conclusion that TREO TM SPF 15, 3-Way protecting lotion is a minimal ocular irritant over 72 hours. Based on these results, the Toxicity Category is IV--Caution.

This study was classified as Core Supplementary according to Guideline series 81-4 and 152-13 because the eyes were not examined for ocular effects at 1 hour (as recommended by the Guidelines), and purity and stability of the test substance were not reported. In addition, an illustrated guide in grading eye irritation (to reduce personal bias and error in scoring the severity of effects) was not used as recommended by the Guidelines.

The reviewers also note that the Quality Assurance Statement was signed, but not dated.

F. APPENDIX

Table 1, Eye Irritation Test Scale of Weighted Scores for Grading the Severity of Ocular Lesion, p. 9-10.

Table 2, Eye Irritation Relative Classification of Test Articles Based on Grading of Irritation, p. 11.

APPENDIX

Page ____ is not included in this copy.

Pages 6 through 8 are not included.

The material not included contains the following type of information:

- ____ Identity of product inert ingredients.
 - ____ Identity of product impurities.
 - ____ Description of the product manufacturing process.
 - ____ Description of quality control procedures.
 - ____ Identity of the source of product ingredients.
 - ____ Sales or other commercial/financial information.
 - ____ A draft product label.
 - ____ The product confidential statement of formula.
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 - ☒ FIFRA registration data.
 - ____ The document is a duplicate of page(s) _____.
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